



Kansas Immunization Program: Storage and Handling Policy

The Vaccines for Children (VFC) Program requires the Kansas Immunization Program (KIP) ensure that VFC provider vaccine management practices are consistent with sound immunization, fiscal, business and medical practices, and do not result in unnecessary costs to the program due to excessive wastage or unaccounted for VFC vaccines. The Centers for Disease Control and Prevention (CDC) have established minimum guidelines detailing the steps of proper vaccine storage and handling. This toolkit is found at:

<http://www.cdc.gov/vaccines/recs/storage/toolkit/storage-handling-toolkit.pdf>

Kansas VFC providers are diligent in their practices to ensure sound vaccine management practices. The Kansas Immunization Program appreciates these efforts. These vaccine management policies are designed to help assure continuation of the VFC program for Kansas children by:

- a. Assisting each provider clinic in quality improvements in VFC vaccine management practices
- b. Reducing wasted vaccines
- c. Ensuring vaccines are stored appropriately so they are stable
- d. Decreasing and/or eliminating unaccounted for vaccines

Clinic policies and procedures shall be updated annually with signature and date. Program staff will review each clinic's policies and procedures at the VFC compliance site visit and/or unannounced visits. VFC providers must have policies and procedures to address management of VFC vaccines in each of the following areas; Vaccine Storage and Handling, Vaccine Ordering, Vaccine Borrowing, Wasted Vaccine and Emergency Management.

Storage and Handling Policy

Appropriate vaccine storage ensures vaccines are stable and will protect against disease.

All VFC providers must keep current and available the CDC Storage and Handling Toolkit.

1. Vaccines must be handled and stored in accordance with the Food and Drug Administration (FDA) approved package insert that is shipped with each product.
2. Refrigerated vaccines must be stored between 35-46 degrees F (2-8 degrees C).
3. Frozen vaccine must be stored at 5 degrees or less F (-15 degrees C).
4. A "dorm-style/bar-style" unit for any VFC vaccine is strictly prohibited.
5. Refrigerated units must be at least large enough to hold the year's largest inventory on the second or lower shelf plus water bottles to stabilize temperature.
6. Storage units should be stand-alone refrigerators and freezers and preferably a vaccine or biological grade unit.
7. Household type units currently in use must have separate doors for the refrigerator and freezer, and each unit must have separate temperature controls. Household units with a single door and/or single temperature control are not acceptable unless the unit is only used for refrigerated vaccine.
8. A "Do Not Unplug" warning sign must be placed next to the electrical outlets for each vaccine storage refrigerator and freezer and on the electrical breaker that services these outlets. Tamper proof plugs are also recommended.

9. A calibrated certified digital thermometer with a minimum and maximum reading capacity and the temperature probe in glycol must be used for every unit storing VFC vaccine. The calibration certification must be current. All calibration certifications must be kept on file for the period of the certification.
10. A backup certified calibrated thermometer must be kept on hand at all times, preferably not in use.
11. The data logger KIP provides meets these calibration certification specifications. (A KIP issued data logger cannot be used as a backup monitoring device.)
12. The temperature of the refrigerator and freezer where the vaccines are stored must be checked and recorded on a temperature log at least twice daily: in the AM when clinic opens and in the PM just before closing (A minimum of 8 hours apart if hours of operation allow). Alarm systems are strongly recommended as back-up for notification of out of range temperatures.
13. If there is a refrigerator or freezer malfunction or power outage, the time interval of the outage needs to be determined as this is critical to determine the stability of the vaccines. Backup generators are strongly encouraged.
14. VFC providers must develop contingency plans to assure vaccine viability in the case of natural disasters, power outages, or other emergencies. Such contingency plans might be a back-up generator or moving vaccines to another location which has a generator. Templates for routine storage, handling and emergency procedures are attached to this policy.
15. Any incident which may call into question the vaccine stability, including incidents of improper vaccine storage and handling, must be reported to KIP by phone and the vaccine manufacturers. The report must include vaccine antigens and length of time and temperature at which vaccine was stored. Not all vaccines are non-viable if the temperature excursion and time factors were minimal. Mark vaccines DO NOT USE and leave refrigerated or frozen until the manufacturer and KIP have been notified. Frozen vaccines are more sensitive to warm temperatures just as refrigerated vaccine is most sensitive to cold temperatures.
16. Once the vaccines are determined to be non-viable, place them in a container and mark DO NOT USE, and see the vaccine Wastage Policy.

Temperature Logs

1. All VFC providers are REQUIRED to maintain a monthly paper temperature log.
2. These temperature logs must be kept on file for a minimum of 3 years and available upon request from KIP
3. Temperature logs are to be filled out completely. This includes: exact time temperatures were check, temperature of unit, staff initials, ect.
4. Temperatures need to be check when the clinic opens and just before closure. If temperatures are out of range, KIP nurse on call needs to be contacted via phone, temperatures will need to return to range, or vaccine moved per emergency plan.

Vaccine Storage Units:

There are several manufacturers of vaccine storage units. Samples of these are found on the KIP website at:

<http://www.kdheks.gov/immunize/storage.htm>

KIP does not endorse any product. The examples are only for demonstration purposes. Each provider is responsible for the terms and conditions of any purchase made.

Program specific documents and policies are found in the Immunization Program Manual at:

<http://www.kdheks.gov/immunize>